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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,372	06/23/2003	Dany Berube	23488-09191	1584
758	7590	09/20/2007		
FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			EXAMINER SONNETT, KATHLEEN C	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/602,372	Applicant(s) BERUBE ET AL.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/31/2007 have been fully considered but they are not persuasive. Applicant argues that Hooven et al. (US 6,517,536) does not disclose (or teach in the case of the rejections of claims 17 and 18 over Truckai et al. (US 2003/0114851) in view of Hooven et al.) a clamp accessory wherein a hinge structure operably attaches the first elongated jaw member to the second elongated jaw member for relative rotation between open and closed configurations along an axis substantially aligned along the elongated direction for selectively effecting closure of the first and second jaw members to operatively engage the ablation device upon a target tissue disposed between the first and second jaw members. However, looking at fig. 28 of Hooven, the first and second jaws are elongated in a direction that is perpendicular to the longitudinal axis of the handle elements (72, 74). (For example, someone could place the device of fig. 28 on a surface so that the handle elements both rest flat on the surface and the elongated jaws point upward off the surface.) The hinge (pin 76) causes the jaws to rotate along the axis of the pin (which is also perpendicular to the longitudinal axis of the handle elements). Therefore this axis of rotation can be considered to be substantially aligned along the elongated direction, which is the direction the jaws are elongated in, since the rotational axis and the elongated direction are parallel to each other and both perpendicular to the longitudinal axis of the handle elements.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claim 1** is rejected under 35 U.S.C. 102(e) as being anticipated by Hooven et al.

Hooven discloses the invention substantially as claimed including a first jaw member having a recess in an inner surface thereof adapted to receive the ablation device therein; a second jaw member opposed to the inner surface of the first jaw member (fig. 32; locations of electrodes [94] and [96], which comprise parts of the ablation device, rest within recesses located on the inner surface of jaw members [78] and [80]); and a structure operably attaching the first jaw member to the second jaw member for selectively effecting closure of the first and second jaw members (fig. 28 [76]); and a transmural system including at least two electrodes disposed near the recess and adapted to selectively transfer electrical signals therebetween through the target tissue to measure at least one of conduction time, conduction distance, conduction velocity, phase angle, and impedance through at least a portion of the targeted biological tissue for monitoring the transmural of an ablation lesion formed therein (col. 8, lines 48-67).

4. The jaws are elongated in a direction perpendicular to the longitudinal axis of the handles. (As discussed above, one could set the device of fig. 28 on a surface such that the handles lay flat on the surface and the jaws curve upward off of the surface.) The hinge structure (pin 76) attaches the two jaw members for relative rotation between open and closed configurations along an axis substantially aligned along the elongated direction. That is, the rotational axis and the direction of the elongated jaws are both perpendicular to the longitudinal axis of the handles and therefore are being considered substantially aligned along the elongated direction.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai in view of Hooven et al. Truckai discloses the invention substantially as claimed including a first jaw member with a recess on the inner surface (fig. 2 [56]) a second jaw member ([55]), and a structure operably attaching the first jaw member to the second jaw member capable of operatively engaging an ablation device upon a target tissue disposed between the jaw members (fig. 4). Truckai also discloses at least two electrodes near the recess (fig. 2, [55] and [56]).

7. Truckai teaches as a part of the transmural system, in an alternative embodiment, sensors in contact with the tissue to measure temperature or impedance through a portion of the tissue (par. 55). Adding these sensors to the device described above would improve the user feedback of the transmural system, therefore it would have been obvious to have the sensors on the device as disclosed above.

8. Truckai also discloses a hinge structure that allows rotation about the axis of the pin, which is substantially perpendicular to the longitudinal axis of the device. Truckai fails to disclose that the jaw members are elongated in a manner that allows the axis of rotation to be aligned along the elongated direction of the jaws.

9. However, Hooven teaches such a configuration. In particular, the elongated jaws of Hoove turn such that they are perpendicular to the longitudinal axis of the device. Jaws that curve away from the longitudinal axis are well known in the art and are used to improve visibility

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for the surgeon as well as making it easier to reach around anatomical structures to grab the desired piece of tissue. Therefore, it would have been obvious to one skilled in the art to modify the device of Truckai to curve the jaws as made obvious by Hooven in order to improve visibility and tissue grasping capabilities of the device. Adding the curved jaws results in jaws which are elongated in a direction perpendicular to the longitudinal axis of the device. The rotational axis of the jaws (around the hinge) is also perpendicular to the longitudinal axis of the device.

10. Regarding claim 18, Truckai further discloses a clamp accessory in which the hinged attachment of the jaw members is disposed to translate laterally to the axis for expanding the spacing between the first and second jaw members in the open and closed configurations (fig. 4, par. 41).

11. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven in view of Green et al. (US 5,476,479). Hooven discloses the invention substantially as stated above, but fails to disclose that at least the first elongated jaw is malleable and formed with a bending disposed therein substantially along the elongated direction to retain a selected shape of the first elongated jaw.

12. Green teaches making jaws of surgical instruments malleable so that they do not need to be fabricated using elaborate and expansive metal working equipment to impart a particular shape to the jaws. As is well known in the art, malleable jaws are advantageous because they can be adapted to fit unique tissue geometries or any needed contour during surgery.

Therefore, it would have been obvious to one skilled in the art to modify the device of Hooven to include malleable jaws as taught by Green in order to gain the advantage of avoiding expensive medical working equipment used to impart a particular shape to the jaws as well as being able to fit unique tissue geometries. Green teaches using a thin piece of malleable material and twisting it into a predetermined position. This thin piece serves as the bending element. In order

to add the malleable feature of Green to the jaws of Hooven, it would be obvious to use such a bending element whose configuration can be easily changed but will retain the remaining elements of the jaw in the selected shape.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,550,130 to Mulier et al. discloses malleable jaws on an electrosurgery device (col. 2 ll. 48-51).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 9/10/2007



GLENN K. DAWSON
PRIMARY EXAMINER